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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/825,219

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EXAMINER

BOESEN, AGNIESZKA

ART UNIT

PAPER NUMBER

1648

MAIL DATE

DELIVERY MODE

01/27/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/825,219	Applicant(s) BOSMAN ET AL.	
	Examiner AGNIESZKA BOESEN	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-34 is/are pending in the application.
- 4a) Of the above claim(s) 21 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 12-20 and 22-33 is/are allowed.
- 6) ☒ Claim(s) 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The Amendment filed June 5, 2008 in response to the Office March 5, 2008 is acknowledged and has been entered. Applicant's response to the Notice to comply with sequence rules filed September 29, 2008 is acknowledged. Claims 17 and 24 have been amended. New claim 34 has been added. Claims 12-20 and 22-34 are under examination in this Office Action.

Claim Rejections - 35 USC § 112

Rejection of claim 17 under 35 U.S.C. 112, first paragraph, **is withdrawn** in view of Applicant's amendment.

New Rejection in view of Applicant's amendment

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

New claim 34 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an immunogenic composition comprising isolated HCV envelope protein or functionally equivalent part thereof, does not reasonably provide enablement for a medicament comprising isolated HCV envelope protein or functionally equivalent part thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Claim is drawn to a medicament comprising isolated HCV envelope protein or functionally equivalent part thereof. A medicament can be interpreted to be a drug; a drug by definition is an agent intentioned for the use in the diagnostics, mitigation, treatment, cure, or

Art Unit: 1648

prevention of disease in humans or in other animals. Pharmaceutical therapies in the absence of *in vivo* clinical data are unpredictable. The specification does not set forth sufficient teachings to allow one skilled in the art to use the claimed medicament for treatment or prophylaxis of infectious diseases. The specification does not provide teachings to establish effective dosages or methods of administration of the claimed recombinant poxvirus treat infections. The specification provides no description or exemplification of how to use the medicament for the prevention, diagnosis, alleviation, treatment, or cure of a disease in the animal to which the substance is administered. No working examples are provided which would provide sufficient guidance to allow one skilled in the art to practice the above embodiments of the invention with a reasonable expectation of success.

The specification speculates generating a vaccine against HCV infection ([0027], [0130], [0188]) while the specification does not provide sufficient enablement for the contemplated vaccines or medicaments comprising HCV envelope proteins. The skilled artisan would have expected that HCV envelope proteins would induce immunogenic immune responses; however the skilled artisan would be required to conduct an undue amount of experimentation in order to determine whether the claimed compositions can be successfully used as medicaments or vaccines.

The instant specification has not taught how to use the HCV envelope proteins as a medicament for treatment or prophylaxis. The specification provides insufficient guidance, which would allow one of skill in the art to predict the efficacy of the claimed medicament with a reasonable expectation of success. As discussed above undue experimentation would be required to practice the claimed invention commensurate with the scope of the claims.

Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. In view of the quantity of experimentation necessary, the limited working examples, the unpredictability of the art, the lack of sufficient guidance in specification, and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

Double Patenting

Rejection of Claims 12-20 and 22-33 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 16 and 34 of U.S. Patent No. 7,048,930 B2 is **withdrawn** in view of Applicant's filing a terminal disclaimer.

Conclusion

Applicant's amendment necessitated the new ground of rejections presented in this Office action. Thus, **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Art Unit: 1648

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AGNIESZKA BOESEN whose telephone number is 571-272-8035. The examiner can normally be reached on 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Agnieszka Boesen/

Examiner, Art Unit 1648

/Bruce Campell/

Supervisory Patent Examiner, Art Unit 1648